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TITLE: Precursors to the Development of Anxiety Disorders in Young Children with Autism Spectrum Disorder

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14. ABSTRACT Sensory over-responsivity (SOR) is characterized by heightened and unusual reactivity to sensory stimuli, such as touch and sound. Community studies suggest that SOR affects up to 16% of school-age children. SOR is also prevalent across a number of neurodevelopmental and psychiatric disorders and recent evidence suggests that it may be a risk factor for emotion dysregulation and anxiety in autism spectrum disorder (ASD). This study aimed to characterize the relationship between SOR, sensory gating, attentional control, and anxiety symptoms in a sample of 3-5 year old children with ASD using parent report, neurophysiological, and observational measures. Initial findings indicate that children with ASD who have clinically significant sensory are at increased risk for also meeting criteria for an anxiety disorder. This finding will provide valuable information in the identification of the early risk factors for anxiety across disorders, which may ultimately guide the development of interventions for and prevention of early onset anxiety, especially among those with ASD					
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I. Introduction

Anxiety disorders are extremely common among individuals with Autism (ASD), yet we still know very little about the early risk factors for anxiety in ASD. Research is beginning to provide some clues regarding early risk factors for anxiety in individuals with ASD, suggesting that sensory over-responsivity (SOR) may be an early emerging risk factor for anxiety in individuals with ASD. Our goal is to identify early risk factors for anxiety disorders in individuals with ASD by conducting an in-depth study of the relationship between SOR, attention, and anxiety symptoms in preschool age children with ASD, using parent report, observational, and EEG measures. This project will help identify the early risk factors for anxiety disorders in ASD, which may ultimately allow interventions to focus on prevention of anxiety. If an association between SOR and anxiety symptoms is confirmed, this study will set the stage for a program of research by our group focused on early detection and prevention of anxiety disorders in young children with ASD.

II. Keywords

Autism, Anxiety, Sensory Over-Responsivity, Attention, EEG

III. Accomplishments

A. Major goals of the project

Specific Aim 1: Evaluate the relationship between Sensory Over-reactivity (SOR) and anxiety symptoms/ disorders in a sample of 3-5 year old children with ASD using parent report, observational, and neurophysiological measures.

	Statement of Work Goal Completion Date	Actual Completion Date or Progress		
		Site 1 - Duke Dawson, Initiating PI	Site 2 - Duke Carpenter, Partnering PI	Site 3 - UNC Boyd, Partnering PI (subcontract with Baranek, USC)
Major Task 1: Prepare regulatory documents and research protocol for IRB and HRPO Approval				
Milestone # 1: IRB approval received at both Duke University and UNC Chapel Hill	12/29/2014	7/21/2014	7/21/2014	6/18/2014
Milestone # 2: HRPO approval received	3/29/2015	8/8/2014	8/8/2014	8/8/2014
Major Task 2: Hiring and training of study personnel on observational measures				
Milestone # 3: Study personnel achieves reliability on the Sensory Processing Assessment, Tactile Defensiveness and Discrimination Test, PAPA, ADOS, and ADI	3/29/2015	7/1/2015	8/1/2015	6/26/2015
Major Task 3: Set up, test, calibrate and pilot experimental measures of attention and neurophysiology				

Milestone #4: Experimental paradigms set-up, tested, and calibrated	3/29/2015	1/22/2015	5/14/2015	5/14/2015
Milestone #5: Study personnel trained in administration of and data collection for attention and ERP tasks	3/29/2015	1/22/2015	5/14/2015	5/14/2015
Milestone #6: Attention and ERP tasks piloted and finalized	4/30/2015	4/3/2015	5/14/2015	5/14/2015
Milestone #7: Study is ready for implementation	4/30/2015	5/14/2015	5/14/2015	5/14/2015
Major Task 4: Participant recruitment and launch of testing				
Milestone # 8: Target enrollment of 30 participants for Year 1 reached	9/29/2015	3/29/2016	3/29/2016	3/29/2016
Major Task 5: On-going enrollment and testing of participants and data collection and processing				
Milestone # 9: Target enrollment of 100 participants by end of Q1 of third year reached and data ready for analysis; Target enrollment was revised based on preliminary analyses of existing data. Target enrollment = 77.	12/29/2016	6/30/2017	6/30/2017	6/30/2017
Milestone # 10: EEG, eye-tracking and sensory observation task data prepared for analysis.	12/29/2016	12/01/2017	12/01/2017	12/01/2017
Major Task 6: Data analysis of SOR and anxiety measures and publication				
Milestone #11: Complete analysis of SOR and anxiety measures	6/29/2017	10/18/2017	10/18/2017	10/18/2017
Milestone #12: Publish results of study on risk factors for anxiety in young children with ASD.	9/29/2017	90%	90%	90%

Specific Aim 2 Evaluate whether anxiety symptoms/disorders mediate the relationship between SOR and a wide range of negative outcomes that have been associated with SOR, namely, levels of impaired adaptive behavior, challenging behaviors (e.g. irritability, aggression), GI symptoms and parental stress.

	Statement of Work Goal Completion Date	Actual Completion Date or Progress		
		Site 1 - Duke Dawson, Initiating PI	Site 2 - Duke Carpenter, Partnering PI	Site 3 - UNC Boyd, Partnering PI (subcontract with Baranek, USC)

Major Task 1: Data analysis of comprehensive set of measures and publication				
Milestone #13: Complete analyses on anxiety as a mediator of the impact of SOR on negative outcomes for children with ASD	6/29/2017	10/18/2017	10/18/2017	10/18/2017
Milestone #14: Publish study on the role of anxiety as a mediator of the impact of SOR on negative outcomes for children with ASD.	9/29/2017	90%	90%	90%

Specific Aim 3 Evaluate whether attentional control, as assessed by a visual attention-shifting task and event-related potentials (ERPs), moderate the relationship between SOR and anxiety symptoms/disorders.

	Statement of Work Goal Completion Date	Actual Completion Date or Progress		
		Site 1 - Duke Dawson, Initiating PI	Site 2 - Duke Carpenter, Partnering PI	Site 3 - UNC Boyd, Partnering PI (subcontract with Baranek, USC)
Major Task 1: Automated coding of visual attention task from videotapes - Work to be conducted by Jordan Hashemi under the supervision of Dr. Sapiro in collaboration with Dr. Carpenter				
Milestone #15: Finalize algorithm for data capture.	3/29/2016	N/A	5/1/2016	N/A
Milestone #16: Apply automated coding to videotapes	12/29/2016	N/A	12/1/2017	N/A
Major Task 2: Data analysis of attention measures and publication - Work to be conducted by Jordan Hashemi under the supervision of Drs. Sapiro, Carpenter, and Dawson				
Milestone #17: Complete data analysis of all eye-tracking and automated coding data	6/29/2017	12/1/2017	12/1/2017	12/1/2017
Milestone #18: Results of study on automated coding as a valid measure of attention in young children with ASD are published	9/29/2017	75%	75%	75%
Major Task 3: Data analysis of SOR measures (parent report, observation, ERP) and publication				
Milestone #19: Complete data analyses of SOR measures	6/29/2017	12/1/2017	12/1/2017	12/1/2017
Milestone #20: Publish results of study validating an auditory ERP measure as a biomarker of SOR in young children with ASD	9/29/2017	80%	80%	80%

B. Accomplishments under the goals of the project (9/30/2016 through 9/29/2017)

Specific Aim 1. Evaluate the relationship between sensory over-responsivity (SOR) and anxiety symptoms/disorders in a sample of 3-5 year old children with ASD using parent report, observational, and neurophysiological measures.

a. Major Task 1: Prepare regulatory documents and research protocol for IRB and HRPO Approval.

Objective 1: Obtain IRB approval from Duke University and UNC Chapel Hill. – completed in Year 1.

Objective 2: Submit amendments, adverse events, and protocol deviations as needed – completed in Year 3.

As the project developed, we continued to amend our IRB to reflect any changes made. Once approved at both sites, amendments to the IRB were also submitted to the HRPO.

b. Major Task 2: Hiring and training of study personnel on observational measures – completed in Year 1.

In addition to the original training of study personnel, we hired new research assistants in Year 2 who have undergone training in cognitive assessments, sensory assessments, and the Preschool Age Psychiatric Assessment. These assistants joined the rest of the research team in reliability training activities.

c. Major Task 3: Set up, test, calibrate and pilot experimental measures of attention and neurophysiology – completed in Year 1.

d. Major Task 4: Participant recruitment and launch of testing.

Objective 1: Provide information and flyers about study to all recruitment sites – completed in Year 3.

We actively recruited subjects through the Duke Center for Autism Subject Registry and distributed study brochures to local agencies and at a number of local events (e.g. Autism Speaks Walks, etc.).

Objective 2: Begin screening and enrolling participants in study – completed in Year 1.

Objective 3: Maintain reliability and quality control on all measures – completed in Year 3.

Training to ensure reliability of the assessments continued throughout the study. Study staff attended monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which took place at the UNC site for this study.

Objective 4: Target enrollment of 30 participants for Year 1 reached – completed Year 2.

e. Major Task 5: Enrollment, testing of participants, data collection, and processing.

Objective 1: Continue active recruitment through on-going communication with recruitment sites – completed in Year 3

We received study referrals from the Duke Center for Autism and Brain Development subject registry and distributed study information at all local autism events (e.g. Walk Now for Autism Speaks, Autism Society of North Carolina Walk, etc.).

Objective 2: Maintain reliability and quality control on all measures – completed in Year 3.

Training to ensure reliability for assessments occurred throughout this study. Study staff attended monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which took place at the UNC site for this study. Observational reliability analyses have been calculated for the sensory assessments, and were found to be in a good range.

Objective 3: Target enrollment of 100 participants by end of Q1 of third year reached and data ready for analysis – completed in Year 3.

We enrolled 77 subjects, and screened 21 additional participants at the completion of this study. Seven additional families expressed interest, but did not reach screening phases. In total, we communicated with 105 participants.

Objective 4: Edit and process EEG data for analysis – completed in Year 3.

Editing and processing of the EEG data is completed. Data analyses are being finalized for publications.

Objective 5: Process eye-tracking data for analysis – completed in Year 3.

Editing and processing of the eye-tracking data is completed. Data analyses are being finalized for publications.

Objective 6: Coding of sensory observation tasks for analysis – completed in Year 3.

Coding of the sensory observation tasks has reached completion.

Objective 7: Data entry, verification, and cleaning for analysis – completed in Year 3.

With the help of Prometheus Research, the Duke Center for Autism and Brain Development has created a database in which all data from this study is stored. All data from this study has been entered into this database.

f. Major Task 6: Data analysis of SOR and anxiety measures and publication.

Objective 1: Conduct data analysis – completed in Year 3.

Forty-six children (71%) with ASD met both symptom and impairment criteria for at least one anxiety disorder. Further, 39 children (60%) with ASD fell 2SDs above typically developing norms for sensory over-responsivity. Overall, there was a significant correlation between mean sensory over-responsivity score and number of anxiety symptoms in children with ASD ($r^2=0.60$, $p<0.0001$). This relationship translated into a 5-fold increased chance of anxiety in children with high levels of sensory over-responsivity in the ASD group (OR 5.5, 95% CI: 1.72, 17.56, $p<0.01$). In the ASD group, sensory over-responsivity significantly increased the odds of GAD by a factor of 6 (OR 6.6, 95% CI: 1.69, 25.55, $p<0.01$) and SAD by a factor of 3 (OR 3.6, 95% CI: 1.26, 10.32, $p=0.02$).

Objective 2: Interpret results and prepare and submit manuscript for publication – Near completion.

Results suggest sensory over-responsivity is strongly associated with anxiety disorders in preschoolers with ASD. In preschoolers with ASD, sensory over-responsivity is associated with both GAD and SAD. This supports our hypothesis that there is a secondary factor (we hypothesized that to be attentional differences) which moderates the relationship between SOR and anxiety in children with autism.

Specific Aim 2 Evaluate whether anxiety symptoms/disorders mediate the relationship between SOR and a wide range of negative outcomes that have been associated with SOR, namely, levels of impaired adaptive behavior, challenging behaviors (e.g. irritability, aggression), GI symptoms and parental stress

a. Major Task 1: Data analysis of comprehensive set of measures and publication

Objective 1: Conduct data analysis – Near completion.

We have begun preliminary analyses of the relationship between negative outcomes and both SOR and anxiety. Evaluation of the extent to which anxiety symptoms mediate the relationship between SOR and negative outcomes is being conducted. Preliminary results support a relationship between observational measures of SOR and several negative outcomes, including picky eating and adaptive social behavior. Similarly, anxiety is related to increased sleep problems in our cohort.

Objective 2: Interpret results and prepare and submit manuscript for publication – Near completion.

Preliminary analyses provide early support for a link between SOR, anxiety, and negative outcomes. In the ASD group, for each increase in Sensory Experiences Questionnaire mean sensory over-responsivity score, the odds of having an anxiety disorder increases by a factor of 5. Findings regarding

the relationship between sensory challenges and executive function differences through sensory responses in preschoolers with autism were presented by Dr. Kimberly Carpenter at the International Meeting for Autism Research in San Francisco, CA. In children with ASD, there seems to be a complex relationship between sensory challenges and executive abilities. Both hypo-responsivity and sensory seeking are associated with difficulties in all domains of executive functioning that were measured. Hyper-responsivity was only associated with shifting and emotional control abilities. Hypo-responsivity is also associated with decreased inhibitory control.

Multiple manuscripts regarding the specific aims of this study are currently in development.

Specific Aim 3. Evaluate whether attentional control, as assessed by a visual attention-shifting task and event-related potentials (ERPs) to a fearful facial expression, moderate the relationship between SOR and anxiety symptoms/disorders.

b. Major Task 1: Automated coding of visual attention task from videotapes.

Objective 1: Apply and calibrate algorithm for data capture – Completed in Year 2.

Objective 2: Apply automated coding to videotapes – Completed in Year 3.

All videos that have been collected as part of this study were processed through the automated coding algorithm once that algorithm has been calibrated to our study population. Videos that were captured after algorithm calibration are in the final stages of analysis.

Objective 3: Enter data for analysis – Completed in Year 3.

The data from the automated coding analyses were deposited in our Center database as it was acquired.

c. Major Task 2: Data analysis of attention measures and publication.

Objective 1: Conduct data analysis of eye-tracking and automated coding data – Near completion.

Both parent report and observational measures of sensory hyper-responsivity were associated with worse scores on the Shifting scale of the BRIEF-P, a parent report measure of attentional shifting. Parent reported sensory hypo-responsivity was also associated with greater dysfunction in the Shifting scale, however this relationship did not remain significant when controlling for age and IQ. Parent reported sensory hypo-responsivity was correlated with higher scores on the Inhibition scale of the BRIEF-P. Finally, emotional control was associated with parent reported hyper- and hypo-responsivity. ADOS severity was not associated with degree of sensory challenges or executive dysfunction.

Objective 2: Interpret results and submit manuscript for publication – Near Completion.

Preliminary results suggest a relationship between SOR and attention in our participants.

d. Major Task 3: Data analysis of SOR measures (parent report, observation, ERP) and publication.

Objective 1: Conduct data analysis of auditory ERP data and SOR data based on parent report and observation data– Near completion.

The analysis of ERP data is in the final stages. We have run preliminary analyses on a sub-sample of 11 children ($M=4.27$, $SD=1.10$, Range= 3-6 yrs). In this subsample, an average of 84.88% of trials (170/200) remained in the dataset. In the grand average ERP, the ratio of the peak to trough amplitudes of P100 between Sound 2 and Sound 1 at the E36 electrode (left hemisphere) was 0.6194. The ratio of the peak to trough amplitudes of P100 between Sound 2 and Sound 1 at the E104 electrode (right hemisphere of the brain) was 1.077. SOR data based on parent report and observation was coded, deemed reliable, and analysis is also in the final stages. As we finalize our analyses, we will explore the relationship between SOR and this ERP data.

Objective 2: Interpret results and submit manuscript for publication – Near completion.

Manuscripts are currently being developed for publication.

C. Opportunities for training and professional development the project has provided

This project has provided training to individuals at a number of levels, including undergraduate, graduate, and post-graduate trainees.

Undergraduate Training: Logan Beyer, a Duke University undergraduate student, received course credit as an Independent Study student on this project between September 2014 and May 2017. In addition, a second independent study student, Jacqueline Emerson, joined the study in January 2016 and will be using the data from this study as the foundation for her Honor's Thesis in the Spring. Both Ms. Beyer and Ms. Emerson received training in autism, anxiety, sensory processing, EEG and eye-tracking data acquisition and analysis, as well as general training in the day-to-day activities associated with scientific research. Additionally, the current funding and associated project have provided both Ms. Beyer and Ms. Emerson with training in scientific writing and principles of scientific data dissemination.

Graduate Training: Kathryn Williams, a graduate student under Dr. Grace Baranek at UNC Chapel Hill, and Adrienne Harris, a graduate student under Drs. Geraldine Dawson, and Nancy Zucker at Duke University, have received training in observational assessment of sensory processing in children with autism as a result of this award. They have also gained experience with study management and oversight.

Post-Graduate Training and Professional Development: Additional training and professional development has been provided to Dr. Kimberly Carpenter, PI of this project. As a result of this project, Dr. Carpenter received training in (a) observational assessment of autism symptoms (ADI and ADOS) and sensory processing (SPA and TDDT) assessment in young children, (b) parent interviewing skills (ADI and PAPA), (c) EEG and eye-tracking data collection and analysis, (d) mentorship of undergraduate and graduate students, and (d) study and personnel management. Additionally, as a direct result of the work supported by this grant, Dr. Carpenter successfully competed for a 2015 NARSAD Young Investigator Award, which supports the research and professional development of early career scientists. She was also promoted to a faculty position within the Department of Psychiatry at Duke University while leading this study.

D. Dissemination of results to communities of interest

Preliminary results from the pilot study on ERP responses were presented at the 2016 North Carolina Psychological Association Undergraduate Research Conference, by Ms. Logan Beyer in a poster entitled "Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism" based on the pilot ERP studies. This event is meant to disseminate undergraduate research projects to undergraduates and professionals from around North Carolina.

This work has been presented at or has been submitted for presentation to the International Society for Autism Research (INSAR) annual meeting:

Carpenter KLH, DeMoss L, Lorenzi J, Williams K, Beyer LN, Riehl H, Glenn E, Egger H, Baranek GT, Dawson G (2017). *The Relationship Between Sensory Challenges and Executive Function Differs by Patterns of Sensory Responses in Preschoolers with Autism*. San Francisco, CA: Annual Meeting of the International Society for Autism Research.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Smith V, Egger HL, Baranek G, Dawson G (2018). *Sensory Over-Responsivity is Associated with Anxiety Disorders is Associated with Anxiety disorders in Preschoolers with Autism and Typical Development*. Rotterdam, Netherlands: Submitted to the Annual Meeting of the International Society for Autism Research.

Dr. Carpenter has also had the opportunity to present preliminary data from this work at a number of venues:

Carpenter KLH (2016). *Anxiety and Autism: Prevalence, Presentation, and Associated Factors*. Durham, NC: Duke Center for Autism and Brain Development Clinical Seminar. (Presenter: Carpenter)

Carpenter KLH (2016). *Anxiety and Autism: Prevalence, Presentation, and Associated Factors*. Durham, NC: Duke Occupational Therapy. (Presenter: Carpenter)

Carpenter KLH (2017). "Anxiety in preschoolers: risk factors, negative outcomes, and comorbidity in autism." Sacramento, CA: MIND Institute Faculty Seminar. (Presenter: Carpenter)

Carpenter KLH (2017). "Sensory Processing and Anxiety in Preschoolers with Autism." Columbia, SC: University of South Carolina Institute for Mind & Brain Colloquium Series Talk. (Presenter: Carpenter)

Finally, a number of papers are currently either in revision or in preparation from this work:

Carpenter KLH, Baranek GT, Copeland WE, Compton S, Zucker N, Dawson G, Egger HL (in Revision). Sensory over-responsivity: an early risk factor for anxiety and behavioral challenges in young children.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Smith V, Egger HL, Baranek G, Dawson G (in prep). Sensory over-responsivity is a risk factor for anxiety and associated challenging behaviors in preschoolers with autism

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Egger HL, Murias M, Baranek G, Dawson G (in prep). Aberrant neural habituation is associated with sensory over-responsivity in preschoolers with and without autism.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Egger HL, Murias M, Baranek G, Dawson G (in prep). Ability to flexibly modulate attention moderates the relationship between sensory over-responsivity and anxiety in children with autism

In addition to scientific presentations, information about this study has been presented at a number of community events, such as meetings of the Durham chapter of the Autism Society of North Carolina.

E. Plans for next reporting period to accomplish goals

Nothing to report.

IV. Impact

A. Impact on the development of the principal discipline(s) of the project

The immediate impact of this project will be the identification of early risk factors for anxiety in ASD. Currently, treatments focus on helping older children and adults with ASD who already suffer from an anxiety disorder, rather than addressing anxiety symptoms when they first begin or even preventing the onset of an anxiety disorder. In fact, very little research on anxiety in preschool age children with ASD has been conducted. Due to the confirmation of the association between SOR and anxiety, this study may ultimately inform interventions that focus on prevention, rather than treatment, of anxiety. Specifically, early behavioral interventions could be customized for children at risk for anxiety to include strategies that could prevent the development of anxiety, offering a more positive outcome for many people with ASD and their families. This study will shed light on the specific ways such interventions should be customized for children with ASD who are at risk for anxiety.

This project will also pilot and validate new methods for measuring SOR and attention that allow for more objective measurement of these behaviors. First, our early pilot study demonstrating a negligible impact of a low-volume cartoon on the N100 ERP response greatly extends the utility of the paired-click paradigm as a measure of SOR in populations of preschoolers with ASD. As researchers continue to explore development of anxiety in children with autism, the ability to use the paired click paradigm to tap relevant variables will likely prove invaluable. Unlike other standard measures of SOR, the paired click paradigm taps the neurobiological basis of sensory sensitivity, and is thus an essential complement to more observational

assessments. Second, the use of automated methods for measuring attention will allow assessment of these behaviors in a more efficient, scalable, and cost-effective manner. Both of these methodological advances will facilitate the translation of findings from the research lab into clinical and educational settings.

B. Impact on the on other disciplines

Sensory over-responsivity (SOR) is characterized by heightened and unusual reactivity to sensory stimuli, such as touch and sound. Community studies suggest that SOR affects up to 16% of school-age children. SOR is also prevalent across a number of neurodevelopmental and psychiatric disorders and recent evidence suggests that it may be a risk factor for emotion dysregulation and anxiety in not only ASD, but also other disorders such as ADHD and anorexia nervosa. This suggests that there is a shared relationship between SOR and anxiety, yet the mechanism underlying this relationship remains unknown. Thus, although the current project focuses on young children with ASD, the findings will have implications for understanding the relationship between SOR, anxiety, and negative outcomes and the development of novel approaches for treating anxiety disorders across the lifespan.

C. Impact on technology transfer

Nothing to report.

D. Impact on society beyond science and technology

Firsthand accounts from people with autism spectrum disorder (ASD) illustrate the impact of sensory over-responsivity (SOR) and anxiety on everyday life. Both SOR and anxiety are extremely common among people with ASD and both have been shown to significantly affect quality of life for the person with ASD and their families. SOR has been associated with higher rates of avoidance, aggression, food selectivity, and lower levels of social and adaptive behavior. A recent study found that early SOR symptoms in a child with ASD can lead to higher levels of family stress and restrictions in family life activities. SOR can also have an impact on oral care, both in the home and dental office. Similarly, the presence of an anxiety disorder has been shown to negatively affect family functioning, friendship development, and school functioning. Later in life, anxiety places adolescents with ASD at risk for social isolation and employment difficulties. Furthermore, higher rates of SOR and anxiety are associated with chronic GI symptoms and sleep disturbance. The results of the current study have the potential to directly influence policy and practice around the early identification and early treatment of SOR and anxiety in children with ASD.

V. Changes/Problems

A. Changes in approach and reasons for change

Nothing to report.

B. Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

C. Changes that had a significant impact on expenditures

Nothing to report.

D. Significant changes in use or care of human subjects

Nothing to report.

E. Significant changes in use or care of vertebrate animals

Nothing to report.

F. Significant changes in use or care of biohazards and/or select agents

Nothing to report.

VI. Products

A. Publications, conference papers, and presentations

a. Journal publications.

Carpenter KLH, Baranek GT, Copeland WE, Compton S, Zucker N, Dawson G, Egger HL (in Revision). Sensory over-responsivity: an early risk factor for anxiety and behavioral challenges in young children.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Smith V, Egger HL, Baranek G, Dawson G (in prep). Sensory over-responsivity is a risk factor for anxiety and associated challenging behaviors in preschoolers with autism

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Egger HL, Murias M, Baranek G, Dawson G (in prep). Aberrant neural habituation is associated with sensory over-responsivity in preschoolers with and without autism.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Egger HL, Murias M, Baranek G, Dawson G (in prep). Ability to flexibly modulate attention moderates the relationship between sensory over-responsivity and anxiety in children with autism

b. Books or other non-periodical, one-time publications.

Nothing to report.

c. Other publications

Nothing to report.

d. Conference papers

Nothing to report.

e. Presentations

Baranek, G. T. (2015). Sensory Features in Children with Autism: Regulatory Mechanisms and Effects on Daily Life. Invited Lecture presented to the SPD Foundation, Orlando, FL. (Oct. 9).

Carpenter KLH, Dawson G, Egger HL, Baranek G (2015) "Sensory Over-Responsivity and Anxiety in Autism." Poster presented at the grand opening of the Duke Center for Autism and Brain Development, Durham, NC.

Beyer L, Dawson G, Egger HL, and Carpenter KLH (2015) "Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism." Poster presented at the Visual Thinking Symposium at Duke University, Durham, NC.

Baranek, G. T. (2015). Understanding the Nature and Impact of Sensory Features in Children with ASD. Invited lecture presented at the 14th Annual Alabama Autism Conference, University of Alabama, Tuscaloosa, AL.

Beyer L, Dawson G, Egger HL, and Carpenter KLH (2016) "Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism." Poster presented at the NC Psychology Undergraduate Conference at the Harris Conference Center, Charlotte, NC.

Beyer L, Kwak H, Dawson G, Murias M, and Carpenter KLH (2016) "Operationalizing Sensory-Sensitivity in Typically Developing Adults with Both EEG and Survey Measures." Poster presented at the Visual Thinking Symposium at Duke University, Durham, NC.

Carpenter KLH (2016). *Anxiety and Autism: Prevalence, Presentation, and Associated Factors*. Durham, NC: Duke Center for Autism and Brain Development Clinical Seminar.

Carpenter KLH (2016). *Anxiety and Autism: Prevalence, Presentation, and Associated Factors*. Durham, NC: Duke Occupational Therapy.

Carpenter KLH (2017). "Anxiety in preschoolers: risk factors, negative outcomes, and comorbidity in autism." Sacramento, CA: MIND Institute Faculty Seminar.

Carpenter KLH (2017). "Sensory Processing and Anxiety in Preschoolers with Autism." Columbia, SC: University of South Carolina Institute for Mind & Brain Colloquium Series Talk. (Presenter: Carpenter)

Carpenter KLH, DeMoss L, Lorenzi J, Williams K, Beyer LN, Riehl H, Glenn E, Egger H, Baranek GT, Dawson G (2017). *The Relationship Between Sensory Challenges and Executive Function Differs by Patterns of Sensory Responses in Preschoolers with Autism*. San Francisco, CA: Annual Meeting of the International Society for Autism Research.

Baranek, G.T. (2017). "Sensory Features in Children with ASD: Studies of Early Identification, Intervention, and Longitudinal Outcomes". Kennedy Center, Vanderbilt University.

Carpenter KLH, Lorenzi J, DeMoss L, Riehl H, Glenn E, Beyer L, Emerson J, Williams KL, Smith V, Egger HL, Baranek G, Dawson G (2018). *Sensory Over-Responsivity is Associated with Anxiety Disorders is Associated with Anxiety disorders in Preschoolers with Autism and Typical Development*. Rotterdam, Netherlands: Submitted to the Annual Meeting of the International Society for Autism Research.

B. Website(s) or other Internet site(s)

<http://autismcenter.duke.edu/research/sensory-processing-and-anxiety-preschool-age-children-autism-spectrum-disorder>

C. Technologies or techniques

Nothing to Report

D. Inventions, patent applications, and/or licenses

Nothing to Report

E. Other Products

Nothing to Report

VII. Participants & Other Collaborating Organizations

A. Individuals that have worked on the project

Name: Geraldine Dawson, PhD, FAPA, FAPS

Project Role: Principal Investigator

Nearest person month worked: 1

Contribution to Project: No Change

Name: Helen Egger, MD

Project Role: Partnering Principal Investigator

Nearest person month worked: 1

Contribution to Project: No Change

Name: Grace Baranek, PhD, OTR/L, FAOTA

Project Role: Partnering Principal Investigator

Nearest person month worked: 1

Contribution to Project: No Change

Name: Kimberly Carpenter, PhD

Project Role: Partnering Principal Investigator; Project Coordinator – Duke Site

Nearest person month worked: 5

Contribution to Project: No Change

Name: Lauren DeMoss, MS, OTR/L

Project Role: Project Co-Coordinator – Duke Site

Nearest person month worked: 5

Contribution to Project: No Change

Name: Logan Beyer

Project Role: Undergraduate Student

Nearest person month worked: 2

Contribution to Project: No Change

Name: Brian Small, MS

Project Role: Interviewer

Nearest person month worked: 1

Contribution to Project: No Change

Name: Hannah Riehl, BS

Project Role: Research Assistant

Nearest person month worked: 6

Contribution to Project: No Change

Name: Elizabeth Glenn, BS

Project Role: Research Assistant

Nearest person month worked: 6

Contribution to Project: No Change

Name: Ashley Freuler, PhD

Project Role: IRB coordination – UNC

Nearest person month worked: 1

Contribution to Project: No Change

Name: John Bulluck, BS

Project Role: Research Associate, UNC

Nearest person month worked: 1

Contribution to Project: No Change

Name: Kathryn Williams, MS
Project Role: Graduate RA, UNC
Nearest person month worked: 1
Contribution to Project: No Change

B. Changes in the active other support of the PD/PI(s) or senior/key personnel

Nothing to report

C. Other organizations involved as partners

Organization name: Center for Autism and Brain Development, Duke University Medical Center
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Center for Developmental Epidemiology, Duke University Medical Center
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Pratt School of Engineering, Duke University
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Duke Pediatric Primary Care
Location of organization: Durham, NC
Partner's contribution to the project: Recruitment support

Organization name: Duke Lenox Baker Children's Health Center
Location of organization: Durham, NC
Partner's contribution to the project: Recruitment support

Organization name: Autism Society of North Carolina
Location of organization: Raleigh, NC
Partner's contribution to the project: Recruitment support